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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,672	01/21/2004	David S. Garvey	102258.137US1	1938
25270	7590	05/04/2005	EXAMINER	
EDWARD D GRIEFF HALE & DORR LLP 1455 PENNSYLVANIA AVE, NW WASHINGTON, DC 20004			AUDET, MAURY A	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/760,672

Applicant(s)

GARVEY ET AL.

Examiner

Maury Audet

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 02/14/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION*****Election/Restrictions***

Applicant's election of Group 45 (in Group B), claims 1-3 and 5, as drawn a method of treating gastrointestinal disorders (species election of peptic ulcer) using the compound N-(3-nitratopivaloyl)S-pivaloyl-cysteine ethyl ester (SPM-4757), in the reply filed on 02/14/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore, the requirement is still deemed proper and is therefore made FINAL. It is noted that Applicant's election of the compound SPM 4757, is an election of the invention (not a species), as noted in the restriction requirement page 6 requiring an election of a single method of using a single peptide as the invention.

Applicant has sought to have Group B, Groups 45 (for treating and/or preventing gastrointestinal disorders), 48 (for treating and/or improving the gastrointestinal properties of COX-2 inhibitors), 51 (for decreasing the recurrence of ulcers), 52 (for improving gastroprotective properties, anti-Helicobacter pylori properties or antacid properties of proton pump inhibitors), and 57 (for improving gastroprotective properties of H2 receptor antagonists) be searched and examined collectively. The Examiner has considered this proposal and is willing to search each of these method Groups together, as drawn to using SPM 4757. Claims 1-3, and 5 are examined on the merits. Claim 4 is withdrawn.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sandrock et al. (US 5,428,061; discussed in related PCT/US02/24923 search report) in view of either Lundy et al. (US 2001/001285; also discussed in related PCT/US02/24923 search report) or Smith et al. (US 5,691,423).

Sandrock et al. teach the use of SPM's (cysteine-containing nitrates), such as SPM-4757 (claim 50) for the treatment of various disorders requiring/benefiting from nitric oxide (NO) and benefiting from the use of NO donors such as SPM-4757 (entire document). Sandrock et al. does not expressly teach the use of SPM-4757 to treat gastrointestinal disorders.

Lundy et al. teaches organic nitrate compounds comprising at least one sulfur atom, for use with COX-2 inhibitors and NSAIDs in methods of treating GI-related problems of caused by COX-2 inhibitors and NSAIDS (abstract, pages 1-2, claims 1, 33, and 36).

Smith et al. teach the use of NO donors (abstract, entire document) and that "[w]ith nitric oxide being additionally implicated in gastric motility, neurotransmission, nociception, and other natural roles, the compositions of this invention may be used for those applications as well" (col. 9, lines 48-52). Smith et al. additionally recites of record other related NO donors, including one of the other related cysteine and sulfur containing NO donor compounds (also cited in Sandrock et al.), SPM-5185 (see "Other Publications" article by Siegfried et al.).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to use SPM-4757 in a method for treating GI disorders in Sandrock et al, because Lundy et al. and Smith et al. each teach the advantageous use of NO donating compounds, including those containing sulfur and/or sulfur and cysteine, to treat GI disorders (including those caused by NSAIDS) and Sandrock et al. teach the use of SPM-4757 to donate NO in disorders requiring NO to achieve therapeutic benefit. Furthermore, Smith et al. explains the benefit of NO in GI disorders, and even makes reference to SPM-5185, a cysteine and sulfur containing SPM also cited in Sandrock et al.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA, 05/01/2005

A handwritten signature in black ink, appearing to read 'CHRISTOPHER R. TATE', with a stylized, looping flourish at the end.

CHRISTOPHER R. TATE  
PRIMARY EXAMINER